

I. Amendments to the Specification

Please replace paragraph [0001] with the following amended paragraph:

This application claims the benefit of U.S. Provisional Application No. 60/242,514, filed October 23, 2000 ~~Oct. 23, 2001~~, hereby incorporated by reference.

Please replace paragraph [0123] with the following amended paragraph:

The pharmacokinetic information for loratadine is available in the literature. The adult oral dosage for loratadine is 10 mg/day. The bioavailability for the drug is 20%, expressed as fraction, 0.20 of the oral dose made available to the blood stream from gastrointestinal absorption. A release rate for a loratadine transdermal delivery system was calculated from this data. 0.20 of the oral 10 mg daily dose provides 2.0 mg of loratadine available into the blood stream. Therefore, an equal dose is required to be delivered transdermally. 2.0 mg/day is converted to 2000 mcg/24 hours. This would require delivery of 83.3 mcg/hour. The largest desirable surface area for a transdermal patch is about 40 cm². Dividing 83.3 mcg/hour/40 cm² by 40, yields a release rate of 2.1 mcg/hour/cm² of transdermal patch surface area. To account for drug elimination, further pharmacokinetic data and physiological data was required. The plasma concentration at steady state for loratadine is 0.002 mcg/ml. The physiological clearance rate is 196,000 ml/hour. The dosing rate is obtained from the product of the steady state concentration of loratadine and a representative clearance rate. This product is 392 mcg/hour. The largest desirable surface area for a transdermal patch is about 40 cm². Dividing 392 mcg/hour/40 cm² by 40, yields a release rate of 9.8 mcg/hour/cm² of transdermal patch surface area. One of skill would expect a larger input rate or flux to maintain a steady state concentration in consideration of the loss of drug in the plasma due to elimination. A confirmatory calculation for flux requires further pharmacokinetic parameters. The volume of distribution for loratadine is 1,660,000 ml and the half-life is 8.4 hours. The elimination rate constant is 0.693/half-life. The product of steady state concentration, volume of distribution and elimination rate constant ~~steady state concentration~~ yields a

Appl. No. 10/045,607

Response dated February 17, 2009

Response to Office Action dated October 14, 2008

rate of 274 mcg/hour. The largest desirable surface area for a transdermal patch is about 40 cm². Dividing 274 mcg/hour/40 cm² by 40, yields a release rate of 6.85 mcg/hour/cm² ~~9.8 mcg/hour/cm²~~ of transdermal patch surface area.